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DEPARTMENT OF HEALTH & HUMAN SERVICES

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

February 10, 2005

Our Reference: JFC International, Inc.
CFN 2911760

Hiroyuki Enomoto, President
Japan Food Corporation
540 Forbes Boulevard
South San Francisco, California 94080

WARNING LETTER

Dear Mr. Enomoto:

On October 28, 29, and November 19, 2004, we inspected your seafood facility, JFC International, Inc., located at 540 Forbes Boulevard, South San Francisco, California. The inspection was conducted to determine your firm's compliance with FDA's seafood Hazard Analysis and Critical Control Points (HACCP) Regulation, Title 21 Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your imported fresh Amberjack and Bonito fish from [redacted]are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health. You may find the Act and the seafood HACCP Regulation through links in FDA's home page at http://www.fda.gov.

During the October 2004 inspection, we found that your firm has a serious HACCP deviation. We listed the HACCP deviation on a Form FDA 483 and discussed it with Ms. Tsuyako Takahagi, QA Assistant Manager, at the conclusion of the inspection.

We are enclosing a copy of the FDA 483 for your reference. Your serious deviation was:

- You must have product specifications that are designed to ensure that fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have product specifications for fresh Amberjack and fresh Bonito fish imported from [redacted]

The above-identified deviation is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure that all seafood products processed and distributed by your firm are in compliance with the Act and the requirements of the federal regulations.

You should take prompt measures to correct the deviations. Failure to promptly correct the deviations noted may result in regulatory action without further notice. Such action includes seizure and/or injunction. In addition, FDA may detain your imported seafood without examination.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific steps you have taken to correct the violation, including an explanation of each step taken to prevent its recurrence. Your response should include copies of any available documentation demonstrating that corrections have been made. If you cannot complete all the corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deficiencies.

Please send your reply to the Food and Drug Administration, Attention: Erlinda N. Figueroa, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, California 94502-7070. If you have questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

Barbara J. Cassens
District Director
San Francisco District

Enclosure: Form FDA 483